Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2185017	04/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Group Of Ar	5 Medical Park Drive, Suite 200, Benton, AR	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory, review of manufacturer's instruction manual, review of the laboratory's temperature and humidity records and interviews with staff, it was determined the laboratory humidity levels was not monitored with the manufacturer's requirement for operating humidity levels for the laboratory's The Avantik QS12 Cryostat. Survey findings include: A) During a tour of the laboratory on 4/28/23 at 08:38 a.m., The Avantik QS12 Cryostat was observed in the main laboratory. B) Review of the manufacturer's instruction user manual for the Avantik QS12 Cryostat revealed an operating humidity requirement "at a max. Relative humidity of 60%". C) Review of the laboratory's room temperature and humidity log for 2021 revealed days recorded of laboratory operation 113. Humidity recorded zero out of 113. D) Review of the laboratory's room temperature and humidity log and for 2022 revealed days recorded of laboratory operation 119. Humidity recorded zero out of 119. E) Review of the laboratory's room temperature and humidity log and for 2023 revealed days recorded of laboratory operation forty-one. Humidity recorded zero out of forty-one. F) In an interview on 4/28/23 at 09:45 a.m. the laboratory staff member (# 4 on the CMS 209 form) confirmed that the minimum humidity requirement for The Avantik QS12 Cryostat was "at a max. Relative humidity of 60%", that the acceptable range defined on the laboratory's

	humidity records for 2021, 2022, and 2023 could not be determine if the laboratory was in operating limits of the manufacturer's requirement.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory and interviews with laboratory staff, it was determined the laboratory had reagents available for use when they had exceeded their expiration date. Survey findings include: A. During a tour of the laboratory, at 11:38 a.m. on 4/28/2023, the surveyor observed one Tissue Marking Dye Red (lot # 095941) on the bench in the staining area. The dye had an expiration date of 3/31/2022. B. In an interview at 12:05 p.m. on 04/28/2023, laboratory personnel #4 (as listed on the CMS 209 form) confirmed the expired reagents were available for use when they had exceeded their expiration date.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory, it was determined the laboratory director failed to provide a safe environment in which employees were protected from chemical and biological hazards. Survey findings include: A. Laboratory Safety Manual titled " General Safety Standards ", stated "No food or drink will be stored in the laboratory work area". B. While in the laboratory, at 09:15 a.m. on 4/28/2023, the surveyor observed multiple types of hard candy on the desk, across from the staining bench and the Avantik QS12 cryostat. C. While in the laboratory, at 09:15 a.m. on 4/28/2023, the surveyor observed laboratory personnel #4 (on the CSM 209 form) brought in cup of water placed on the desk, across from the staining bench and the Avantik QS12 cryostat. D. While in the laboratory, at 10:45 a. m. on 4/28/2023, the surveyor observed laboratory personnel #4 (on the CSM 209 form) brought in Coke can and placed on the desk, across from the staining bench and the Avantik QS12 cryostat.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of the CMS-209 form presented at the time of the survey, a review of personnel records for five personnel listed on the form CMS-209, and through interviews with laboratory staff, it was determined two of four testing personnel failed to have written authorization to perform testing without direct supervision. Survey findings include: A. Through a review of the CMS- 209 form, it was determined that all personnel were designated as testing personnel. B. A review of personnel records for five personnel listed on the form CMS-209 revealed that two of five failed to have written authorization to perform testing without direct supervision. Laboratory personnel # 4 and # 5, did not have a written authorization to perform testing without direct supervision. C. In an interview at 09:38 a.m. on 4/28/2023, laboratory personnel # 4 (listed on the form CMS-209) confirmed that the laboratory did not have documented authorization for testing for employees performing testing.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Through a review of personnel files, lack of documentation, and interviews with laboratory staff, it was determined the technical supervisor failed to evaluate the competency of personnel at least semiannually in the first year of testing. Survey findings follow: A. A review of five personnel records revealed that employee #5 (as listed on the form CMS-209) had new employee training documented on 1/26/2021. The only competency evaluation documented for employee #5 was dated 10/2022. Although the employee has been testing for over one year (20 months) only one competency was available upon request. B. In an interview, at 12:09 p.m. on 4/28 /2023, employee #4 (as listed on the form CMS-209) confirmed the competency of employee #5 had not been documented semiannually the first year that he tested patients.